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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,123	10/20/2000	Paul R. Lesch JR.	8066-057	6851

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EXAMINER

THOMPSON, KATHRYN L

ART UNIT PAPER NUMBER

3763

DATE MAILED: 03/01/2004

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/692,123

Applicant(s)

LESCH, PAUL R.

Examiner

Kathryn L Thompson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-13, 15-17 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 18-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-13, 15-17, 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 16.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Newly submitted claims 18-28 are directed to inventions that are independent or distinct from the invention originally claimed for the following reasons: Claims 18-22 are drawn to a method of injecting a medicament and not to the apparatus (medicament cartridge) itself. Claims 23-28 are drawn to a non-elected species as disclosed in Figure 1.

Since applicant has received an action on the merits for the originally presented invention, (an apparatus and Figures 7-10), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 18-28 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-13, 15-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

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was filed, had possession of the claimed invention. There is nowhere in the specification any mention of a jet injector.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

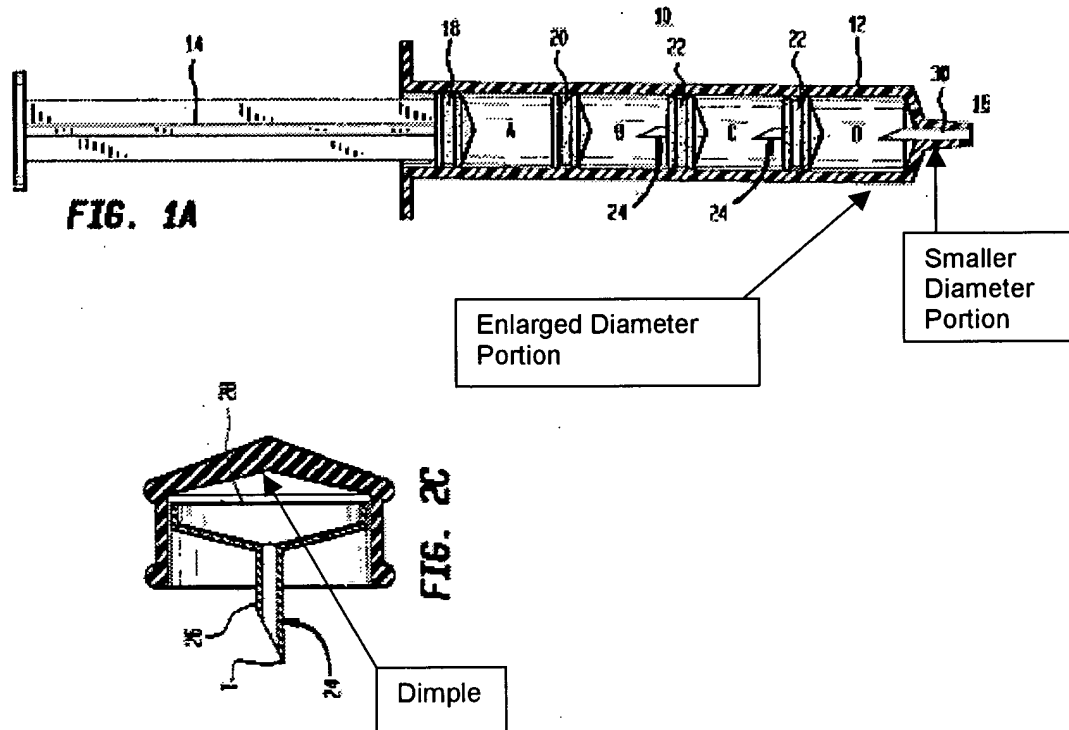
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 6, 7, 9-13,16, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Richmond (US 5,102, 388). Richmond discloses a jet injector comprising a medicament cartridge comprising a medicament, a tube, a needle having a piercing end with a bevel extending into the lumen, a first stopper within and against the lumen, a second stopper within and against the lumen, wherein movement of the first stopper with respect to the tube causes the piercing end of the needle to pierce the first stopper and movement of the second stopper with respect to the tube compresses the medicament held between the second stopper and the first stopper so that the medicament is expelled through the fluid pathway, wherein the lumen has a portion with an enlarged diameter (See Figure 1A Below) and further comprising a third stopper within the lumen located between the second stopper and the enlarged diameter, wherein the first stopper has a frustroconical shape, wherein the second stopper has a medicament contacting surface configured and dimensioned to mate with the frustroconical shape of the first stopper (Figure 2D), wherein the first stopper has a

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dimple and narrow cross-section where the needle penetrates the first stopper (See Figure 2C Below), wherein the cartridge is configured for use in combination with an injection device (14) for firing the cartridge to expel the medicament.



Claims 1, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Huber (US 2,688,967). Huber discloses a medicament cartridge for an injection system comprising a medicament, a tube, a needle having a piercing end with a bevel extending into the lumen and an injecting tip extending beyond the second end of the tube wherein the injecting tip has a bevel, a first stopper, a second stopper, wherein movement of the first stopper with respect to the tube causes the piercing end of the needle to pierce the first stopper and movement of the second stopper with respect to

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the tube compresses the medicament held between the second stopper and the first stopper so that the medicament is expelled through the fluid pathway (Figure 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Richmond in view of Vetter (US 5, 139, 490). Richmond teaches all of the claimed limitations except a medicament containing insoluble particles. Vetter discloses a medicament containing insoluble (undissolved) particles (Column 3, Lines 22-30). It would have been obvious to one with ordinary skill in the art to combine the teachings of Vetter with the invention of Richmond in order to be able to use the claimed medicament cartridge with lyophilized medicament.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huber in view of Tanaka et al (US 5,605,542). Huber discloses all of the claimed limitations except a portion of the lumen with an enlarged diameter, the third stopper being located between the second stopper and the enlarged diameter portion, wherein movement of the third stopper to the enlarged diameter portion allows the first and second medicament components to mix. Tanaka et al teaches a portion of the lumen with an enlarged diameter (Column 4, Lines 37-41), the third stopper being located between the second

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stopper and the enlarged diameter portion, wherein movement of the third stopper to the enlarged diameter portion allows the first and second medicament components to mix (Column 5, Lines 24-34). It would have been obvious to one with ordinary skill in the art to use the teachings of Tanaka et al to modify the invention of Huber with an enlarged diameter portion in the lumen in order to create a means for mixing different medicaments.

Response to Arguments

Applicant states that there is no previous restriction or election requirement in the file and that Examiner did not provide sufficient grounds to make the withdrawal of claims 18-22 in her final Office Action. Examiner respectfully disagrees. Firstly, Examiner notes the restriction/election requirement of May, 2002, along with the first non-final office action. Secondly, the following is provided for the Applicant in the hopes of further clarifying and justifying Examiner's withdrawal of Claims 18-22 and Claims 23-28.

MPEP 818.01 Election Fixed by Action on Claims

Election becomes fixed when the claims in an application have received an action on their merits by the Office.

MPEP 818.02 Election Other Than Express

Election may be made in other ways than expressly in reply to a requirement as set forth in MPEP § 818.02(a) and § 818.02(c).

MPEP 818.02(a) By Originally Presented Claims

Where claims to another invention are properly added and entered in the application before an action is given, they are treated as original claims for purposes of restriction only.

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The claims originally presented and acted upon by the Office on their merits determine the invention elected by an applicant in the application, and in any request for continued examination (RCE) which has been filed for the application. Subsequently presented claims to an invention other than that acted upon should be treated as provided in MPEP § 821.03.

MPEP 821.03 Claims for Different Invention Added After an Office Action
Claims added by amendment following action by the examiner, MPEP § 818.01, § 818.02(a), to an invention other than previously claimed, should be treated as indicated by 37 CFR 1.145.

37 CFR 1.145. Subsequent presentation of claims for different invention.

If, after an office action on an application, the applicant presents claims directed to an invention

distinct from and independent of the invention previously claimed, the applicant will be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to

reconsideration and review as provided in §§ 1.143 and 1.144

The action should include form paragraph 8.04.

8.04 Election by Original Presentation

Newly submitted claim [1] directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: [2]

Since applicant has received an action on the merits for the originally presented invention,

this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim [3] withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Of course, a complete action on all claims to the elected invention should be given.

Note that the above practice is intended to have no effect on the practice stated in MPEP

§ 2303.

An amendment canceling all claims drawn to the elected invention and presenting only claims drawn to the nonelected invention should not be entered. Such an amendment is nonresponsive. Applicant should be notified by using form paragraph 8.26.

8.26 Canceled Elected Claims, Non-Responsive

The amendment filed on [1] canceling all claims drawn to the elected invention and presenting only claims drawn to a non-elected invention is non-responsive (MPEP § 821.03). The remaining claims are not readable on the elected invention because [2].

Since the above-mentioned amendment appears to be a bona fide attempt to reply, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.

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Applicant argues that Claim 1 has been amended to claim a jet injector, that it is supported in the originally filed abstract of the application, and that the preamble must be considered as a structural limitation. Examiner respectfully disagrees. Firstly, there is no support in Applicant's specification of a jet injector. Secondly, the recitation jet injector has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Clearly, all the positively recited structural limitations of the claims are met by the prior art of record.

As Applicant confirms in his response, new claims 23-28 are supported by the embodiment of Figure 1, which is a non-elected species. Therefore, Claims 23-28 are withdrawn from further prosecution.

Conclusion

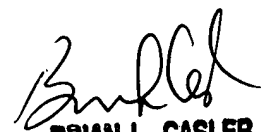
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L Thompson whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KLT



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